**Purpose:** This tool provides best practices for rural hospitals (CAH/RRC/SCH) to verify 340B Program eligibility through routine self-audits.

**Background:** CAH/RRC/SCH hospitals must meet the eligibility requirements of 42 USC 256b(a)(4)(N,O) to participate in the 340B Drug Pricing Program. A key component of a compliant 340B Program is routine monitoring and auditing of the entity’s eligibility status, which allows the entity to evaluate its compliance with 340B Program requirements and to identify areas for improvement.

**This self-audit tool is part of a series focusing on three compliance elements**:

**1. Eligibility**

**2. Prevention of Diversion**

**3. Prevention of Duplicate Discounts**

Prior to completing the Eligibility Self-Audit Tool, covered entities are encouraged to:

* Map their 340B drug universe (this tool is available in [Word](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.docx) and [Excel](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.xlsx))
* Complete the [Self Audit: Policy and Procedure](https://www.340bpvp.com/Documents/Public/340B%20Tools/self-audit-policy-and-procedure.docx)

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| **340B Program Eligibility Compliance Self-Audit Tool** | |
| 1. Parent entity’s name |  |
| 1. Parent entity’s 340B ID |  |
| 1. Parent entity’s physical address (including suite number, if applicable) |  |
| 1. Date of the LAST self-audit |  |
| 1. Date of THIS self-audit |  |
| 1. Name and title of individual completing THIS self-audit |  |
| 1. Signature of individual completing THIS self-audit |  |
| 1. Summary of results:   **Note areas for improvement identified** | |
| 1. Actions to be taken: | |

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| **Compliance Element: Ensure that the entity meets all 340B Program eligibility requirements.**  *Rural hospitals must meet eligibility requirements of 42 USC 256b(a)(4)(N,O) to participate in the 340B Drug Pricing Program.* | | | | | |
| **340B Eligibility and Program Requirements** | | | | | |
| **Assessment Questions** | **Yes** | | **No** | **N/A** | **Unsure** |
| 1. **For SCH and RRC only (mark N/A if CAH):**   **Does the parent covered entity have a calculated disproportionate share**  **percentage greater than or equal to 8% on its most recently filed Medicare**  **Cost Report?**  Disproportionate share percentage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Worksheet E, Part A: Line 33  Date of most recently filed Medicare Cost Report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Worksheet S signature block time/date  Attach Medicare Cost Report to self-audit | | | | | |
| *If response is “No” or “Unsure,” explain:* | | | | | |
| 1. **Is the parent covered entity:** 2. Owned or operated by a state or local government? 3. A public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government? 4. A private nonprofit hospital that has a contract with a state or local government to provide health care services to low-income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the state plan under this title?   Classification (select a, b, or c): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Attach a copy of required documentation supporting the classification per the [340B Program Hospital Registration Instructions](https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf).  HRSA requires hospitals to have the necessary documentation that demonstrates they meet statutory requirements for eligibility.  \*Starting April 1, 2019, HRSA will be conducting additional program integrity reviews and hospitals may be asked to submit these documents upon registration. | |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* | | | | | |

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| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **340B ELIGIBILITY SITE VERIFICATION**  **Table 1**   * List the name of the parent and off-site outpatient locations (child sites) using 340B drugs in column 1   (*Note: “Locations using 340B drugs” includes locations that purchase, dispense, administer, or otherwise generate prescriptions for dispensing elsewhere)*   * In column 2, list the 340B ID associated with each site * Compare the information in columns 1 and 2 with the covered entity’s most recently filed Medicare Cost Report (MCR) to complete column 3 * Compare the information in columns 1 and 2 with the covered entity’s HRSA Office of Pharmacy Affairs Information System (340B OPAIS) records to complete column 4 | | | | | | | **Table 1**  **340B Eligibility Site Verification**  **(attach actual data to substantiate eligibility of each site)** | | | | | | | **(1)**  **Name of site** | **(2)**  **340B ID** | **(3)**  **Site listed as reimbursable clinic with associated costs/charges on most recently filed MCR?** | | **(4)**  **Site either at same physical location as parent hospital or registered on 340B OPAIS if offsite from parent hospital?** | |  | | **YES** | **NO** | **YES** | **NO** | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | | | | |
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| **Table 1: Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Are all sites that use (procure, dispense, administer, or prescribe) 340B drugs listed as reimbursable, with associated outpatient costs and charges, on the covered entity’s Medicare Cost Report (MCR)?**   *(All clinics/departments/services located off-site of the parent hospital, regardless of whether those clinics/departments are in the same building [including another hospital], must be listed as reimbursable cost centers with associated outpatient costs and charges on the covered entity’s most recently filed Medicare Cost Report [typically identified via Medicare Cost Report Worksheet A, lines 50–118].)*   1. List sites using 340B drugs (*refer to Table 1, column 1)* 2. Compare the list to the entity’s MCR Worksheet A to verify that sites are listed as reimbursable. 3. Compare the list to the entity’s MCR Worksheet C to verify that sites have associated outpatient costs and charges   Answer “Yes” to the question only if all the answers are “YES” in column 3, “Site listed as reimbursable clinic with associated costs/charges on most recently filed MCR?”  For more information on hospital off-site outpatient facility registration requirements, view the [340B Program Hospital Registration Instructions](https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf). |  |  |  |  |
| *If response is “No” or “Unsure,” specify which location and explain:* | | | | |
| 1. **Are all sites that use (procure, dispense, administer, or prescribe) 340B drugs at same physical location as parent hospital or registered on 340B OPAIS?**   *(All clinics/departments/services located off-site of the parent hospital, regardless of whether those clinics/departments are in the same building [including another hospital], must be registered as child sites of the parent 340B-eligible hospital if the covered entity purchases and/or provides 340B drugs to patients of those facilities.)*  Answer “Yes” to the question only if all the answers are “YES” in column 4, “Site either at same physical location as parent hospital or registered on 340B OPAIS if offsite from parent hospital?” |  |  |  |  |
| *If response is “No” or “Unsure,” specify which location and explain:* | | | | |

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| **SITE INFORMATION: 340B OPAIS VERIFICATION**  **Table 2**   * List the name and 340B ID of the parent and off-site outpatient locations in columns 1 and 2, respectively *(refer to Table 1)* * Identify the physical address (including suite number, if applicable) of the parent and off-site outpatient locations in column 3 * Identify the bill-to, ship-to addresses (including entity-owned pharmacies) associated with the parent and off-site outpatient locations in column 4 * List the name, title, and phone number of the authorizing official and primary contact of the parent and off-site outpatient locations in columns 5 and 6, respectively * Compare the information in columns 1–6 with the covered entity’s 340B OPAIS records to complete column 7 | | | | | | | |
| |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Table 2**  **Site Information: 340B OPAIS Verification** | | | | | | | | | **(1)**  **Name of Site** | **(2)**  **340B ID** | **(3)**  **Physical address** | **(4)**  **Bill-to, ship-to addresses** | **(5)**  **Authorizing official (including phone #)** | **(6)**  **Primary contact (including**  **phone #)** | **(7)**  **All information matches information listed on 340B OPAIS?** | | | **YES** | **NO** | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | | | | | | | | |
| **Table 2: Assessment Question** | | **Yes** | | **No** | **N/A** | | **Unsure** |
| 1. **Is information maintained on the covered entity’s 340B OPAIS accurate?**   Answer “Yes” to the question only if all the answers are “YES” in column 7, “All information matches information listed on 340B OPAIS?” in Table 2. |  | |  | | |  | |
| *If response is “No” or “Unsure,” explain:* | | | | | | | |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.*

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